## **Complete Summary**

#### **GUIDELINE TITLE**

ACR Appropriateness Criteria<sup>™</sup> for renal cell carcinoma staging.

## BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Urologic Imaging. Renal cell carcinoma staging. Reston (VA): American College of Radiology (ACR); 2001. 5 p. (ACR appropriateness criteria). [33 references]

## COMPLETE SUMMARY CONTENT

**SCOPE** 

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## **SCOPE**

## DISEASE/CONDITION(S)

IDENTIFYING INFORMATION AND AVAILABILITY

Renal cell carcinoma

#### **GUIDELINE CATEGORY**

Diagnosis Evaluation Screening

#### CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nephrology
Oncology
Radiation Oncology
Radiology
Urology

#### INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

#### GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic examinations in the staging of renal cell carcinoma

#### TARGET POPULATION

Adult patients with renal cell carcinoma

#### INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Chest radiography
- 2. Abdominal computed tomography (CT) with intravenous (IV) contrast
- 3. Abdominal magnetic resonance imaging (MRI)
- 4. Abdominal ultrasound (US)
- 5. Angiography
- 6. Magnetic resonance angiography (MRA)/computed tomography angiography (CTA) of renal vessels
- 7. Inferior venacavography
- 8. Bone scan
- 9. Chest computed tomography
- 10. Excretory urography
- 11. Brain magnetic resonance imaging
- 12. Bone survey

#### MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in the staging of renal cell carcinoma staging

## METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

#### NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVI DENCE

Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

## RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

<u>Clinical Condition</u>: Renal Cell Carcinoma Staging (Renal Mass Previously Identified)

Radiologic Exam Procedure	Appropriateness Rating	Comments
Chest radiography	9	
Abdominal CT with IV contrast	8	
Abdominal MRI	8	May become primary technique in future. Useful when CT is equivocal (see exceptions).
Abdominal ultrasound	4	Indicated if CT cannot be performed.  Depends on patient size and expertise of operator.
Angiography	3	
MRA/CTA of renal vessels	3	May be used to identify accessory renal arteries prior to nephrectomy.
Inferior venacavography	3	Useful for large bulky tumors with adenopathy or when other studies are equivocal.
Bone scan	3	Indicated when patient has localized bone pain or elevated alkaline phosphatase, a large tumor, or evidence of metastatic disease.

Radiologic Exam Procedure	Appropriateness Rating	Comments	
Chest CT	3	Useful if chest radiograph is abnormal.	
Excretory urography	2		
Brain MRI	2	Not highly appropriate unless brain metastases are suspected.	
Bone survey	1	Selected plain films are indicated when the patient has localized bone pain.	
Appropriateness Criteria Scale			

Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate

Abbreviations: CT, computed tomography; IV, intravenous; MRI, magnetic resonance imaging; MRA, magnetic resonance angiography; CTA, computed tomography angiography

Renal cell carcinoma (RCC) represents about 2% to 3% of all human malignancies. In 1998, approximately 29,900 new cases of renal cancer were diagnosed, and there were 11,600 deaths. Men are more commonly affected than women in a 2:1 to 3:1 ratio. Metastatic disease at presentation varies with the patient population but typically occurs in 23% to 33%. The most common sites of distant metastases in descending order are the lung, bone, skin, liver, and brain.

The most effective treatment for RCC is radical nephrectomy, which involves node dissection and complete removal of the kidney and Gerota's fascia. Prognosis is related to size of tumor and stage. There are two methods of staging in common use. Robson's classification is more commonly used in the United States, while the tumor node metastases (TNM) classification is more commonly employed internationally. See the original guideline document for a tabular comparison of the two classifications.

Approximately 33% of cases present in Stage I, 10% in Stage II, 25% in Stage III, and 33% in Stage IV. Median 5-year survival rates are 73% for Stage I, 68% for Stage II, 51% for Stage III, and 20% for Stage IV.

Prognosis is related to size of the primary tumor as well. In one large study, T1 (<2.5 cm) tumors produced a 100% 5-year survival, whereas tumors >10 cm in diameter yielded a median survival of 27% at 5 years.

Only 5% to 10% of patients present with the classic triad of flank mass, hematuria, and pain. Since the widespread use of ultrasound (US), computed tomography (CT), and magnetic resonance imaging (MRI), RCCs are increasingly discovered when they are small and therefore at lower stage. These incidentally discovered tumors have a much better prognosis than symptomatic tumors.

Preoperative staging is important to the surgeon in planning the procedure. Both CT and MRI are inaccurate in identifying perinephric fat involvement (T3a).

However, since the perinephric fat is removed during surgery, this has not proven to be a significant limitation.

Not only must the involvement of the renal veins and inferior vena cava (IVC) (T3b or T3c) be identified, but the cephalic extent of the tumor must also be correctly assessed. Intra-atrial thrombus may require cardiac bypass. Intrahepatic caval thrombus may require open thrombectomy or graft placement. Thrombus limited to the renal vein ostia may be "milked" back into the vein without the need to open the vein. Therefore, accurate assessment of caval thrombus is important.

Dynamic enhanced CT is the most commonly employed method of identifying caval thrombus. Studies have shown that the technique employed influences the success of CT, particularly with regard to the speed of scanning and rate of contrast media administration. Signs suggestive of renal vein or caval thrombus include filling defects, enlargement of the vessel, and rim enhancement. Venous anomalies should be sought, specifically in the retroaortic left renal vein or the circumaortic left renal vein. Computed tomography is 50% to 100% sensitive for detecting caval thrombus according to the literature, but with good technique achieves 85% to 91% sensitivity routinely. Problems occur with technically inadequate boluses of contrast media, motion and flow artifact (especially with foot injections), and renal insufficiency.

Magnetic resonance imaging (MRI) is 83% to 100% sensitive for tumor thrombus but routinely achieves 90% to 100% sensitivity for tumor thrombus with modern equipment and thus is slightly more sensitive than CT and more accurately assesses the cephalic extent of the thrombus. Pitfalls of MRI include large tumors compressing the vena cava and flow-related artifacts, which can be reduced with appropriate saturation pulses. With bright blood techniques, rapid or turbulent flow can also lead to artifacts. Intravenous contrast may be helpful in this setting.

Most authors consider MRI superior to CT for detecting tumor thrombus. However, if the CT is of good quality and the vein is clearly seen, MRI is usually not needed. Other techniques include US, which is approximately 50% to 75% sensitive for caval thrombus.

Ultrasound (US) is limited in obese patients and is commonly limited due to bowel gas, which interferes with the ability to image the renal vein-IVC junction.

Cavography is approximately 85% to 100% sensitive for detecting caval thrombus and is equal to MRI in accuracy. In patients who cannot undergo MRI or for whom the MRI is equivocal, cavography is a suitable alternative. Angiography has proved insensitive for tumor thrombus.

For TxN+ disease (lymph node involvement), CT and MRI are approximately equal and both are superior to ultrasound (US). US is often obscured by bowel gas. However, from a surgical perspective, the identification of nodes is less important because the nodes must be sampled at the time of surgery. CT-guided aspiration biopsies can be performed if desired for documenting nodal metastases; however, this is rarely needed. Imaging is important for the preoperative detection of bulky adenopathy, which might complicate the surgical approach. This is especially true for laparoscopic nephrectomies in which both the vascular anatomy and the nodal pathology may be poorly visualized. Accurate preoperative information becomes

even more important, emphasizing the need for computed tomography angiography (CTA) or magnetic resonance angiography (MRA) prior to such a procedure.

T4 M0-1 disease (metastatic disease with contiguous invasion) is also important to the surgeon. Common sites of contiguous organ invasion include the liver, diaphragm, psoas muscles, pancreas, and bowel. Neither CT nor MRI is ideal, because it is impossible at times to distinguish immediately adjacent but not invasive tumor from directly invasive tumor; however, both techniques perform well, with a sensitivity and specificity >90%. The multiplanar capabilities of MRI can be useful in this regard; however, neither technique always assesses liver or diaphragmatic invasion correctly. Angiography can also be misleading since tumors can recruit vessels from the liver or elsewhere without the tumor actually invading the organ.

T4 M1 N+ disease (distant metastases) principally affects the chest, bone, liver, and brain. Routine chest radiographs are considered necessary, but studies have shown that the yield from routine chest CT is too small to warrant its use. For larger tumors, chest CT is justified. When the chest radiograph is suspicious or positive, chest CT is useful for confirming or excluding metastases and defining the extent of disease.

Similarly, neither routine bone scans nor bone surveys appear justified. If the patient has an elevated alkaline phosphatase, bone pain, or an extremely large and aggressive tumor, bone scans may be helpful but in most cases are unwarranted. Furthermore, brain MRI does not appear routinely justified but is indicated when neurologic symptoms are present, if the primary tumor is large or if other metastatic disease is already present.

Thus, the routine work-up for renal cancer staging should include a dynamic-enhanced CT performed on a state-of-the art unit and a chest radiograph. If there is a question regarding the patency of the renal vein or IVC or if the CT is technically inadequate, MRI should be performed. MRI should be considered in any patient who cannot receive intravenous iodinated contrast media due to renal insufficiency or allergy. Ultrasound is a valid alternative, but its success depends on the patient's size, the quality of the equipment, and the experience of the observer. If the tumor is bulky and questions remain after MRI, cavography should be considered.

Chest radiography should be used as a screen for metastatic disease in RCC. For patients with a positive chest radiograph, chest CT should be obtained. For large or very locally aggressive renal tumors, chest CT should be considered even with a negative chest radiograph since the frequency of metastases is higher in these patients and the lung is the most common site of metastasis from renal cancer.

Bone scans and brain MRI should be reserved for patients with abnormal blood chemistries, symptoms, or large, locally aggressive or metastatic primary renal cancers.

Angiography is no longer used to diagnose renal cancers; however, it retains an important role in surgical planning. Angiographic depiction of the renal vessels is helpful in identifying accessory renal vessels and provides a "road map" for the

surgeon. For large tumors in which embolization is desired or where the organ of origin is in question, angiography is useful. Both MRA using dynamic-enhanced 3D time-of-flight methods and CTA have been shown to be accurate substitutes for conventional angiography for identifying accessory renal vessels prior to partial or laparoscopic nephrectomies.

## Anticipated Exceptions

In patients with intravenous (IV) contrast allergies or renal insufficiency, MRI and/or US may be preferred to CT. MRI is superior to US in evaluating adenopathy, determining the organ of origin of the mass, diagnosing intracaval and renal venous thrombus, and demonstrating bone metastases.

In patients with abnormal chest radiographs suspicious for metastases, chest CT is helpful for confirmation.

In patients with bone pain or elevated alkaline phosphatase, bone scans and plain radiographs of the symptomatic areas are probably indicated.

In patients with symptoms referable to the central nervous system (e.g., headaches, seizure, change in mental status), cranial MRI with gadolinium enhancement is probably indicated.

#### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

- Appropriate evaluation of radiographic examinations for renal cell carcinoma staging
- Imaging is important for the preoperative detection of bulky adenopathy, which might complicate the surgical approach.
- Patients with incidentally discovered tumors have a much better prognosis than patients with symptomatic tumors.

## POTENTIAL HARMS

• Computed tomography (CT) and magnetic resonance imaging (MRI) are inaccurate in identifying perinephric fat involvement.

- Pitfalls of magnetic resonance imaging include large tumors compressing the vena cava and flow-related artifacts, which can be reduced with appropriate saturation pulses.
- Ultrasound (US) is limited in obese patients and is commonly limited due to bowel gas, which interferes with the ability to image the renal vein-inferior vena cava (IVC) junction.

## QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other coexistent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

#### IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

**Getting Better** 

IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Urologic Imaging. Renal cell carcinoma staging. Reston (VA): American College of Radiology (ACR); 2001. 5 p. (ACR appropriateness criteria). [33 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### DATE RELEASED

1995 (revised 2001)

## GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

#### SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria $^{\text{TM}}$ .

## **GUI DELI NE COMMITTEE**

ACR Appropriateness Criteria™ Committee, Expert Panel on Urologic Imaging

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

**GUIDELINE STATUS** 

This is the current release of the guideline. It updates a previous version: Choyke PL, Amis ES, Bigongiari LR, Bluth EI, Bush WH, Fritzsche P, Holder L, Newhouse JH, Sandler CM, Segal AJ, Resnick MI, Rutsky EA. Renal cell carcinoma staging. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun; 215(Suppl): 721-5.

All Appropriateness Criteria<sup>™</sup> topics are reviewed annually and updated as appropriate.

#### GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Portable Digital Assistant (PDA): ACR Appropriateness Criteria<sup>™</sup> - Anytime, Anywhere (PDA version) is available from the <u>ACR Web site</u>.

Print copies: Available from the American College of Radiology, Department of Quality & Safety, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

#### AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 American College of Radiology ACR Appropriateness Criteria<sup>™</sup> introduction. Reston (VA): American College of Radiology; 6 p. Available in Portable Document Format (PDF) from the ACR Web site.

#### PATIENT RESOURCES

None available

#### NGC STATUS

This summary was completed by ECRI on May 6, 2001. The information was verified by the guideline developer on June 29, 2001. This summary was updated by ECRI on September 8, 2004. The updated information was verified by the guideline developer on October 8, 2004.

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